K122519

MAY 2 1 2013

Attachment 4

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Preparation date : Feb 15, 2013

1. Submitter	DIO Corporation 66, Centumseo-ro, Haeundae-gu, Busan, Korea Tel. : 82-51-745-7777 Fax. : 82-51-745-7778
2. US Agent / Contact Person	DIO, USA Tim C.J. Lee 3540 Wilshire Blvd. #1104 Los Angeles, CA 90010, USA Tel. : 213-365-2875 Fax. : 213-365-1595
3. Trade Name	DIO UF HSA Internal Sub-Merged Implant System
4. Common Name	Dental Implant
5. Classification Name	Endosseous Dental Implant 21 CFR 872.3640 ClassII DZE, NHA
	Endosseous Dental implant abutment 21 CFR 872.3640 ClassII DZE, NHA
6. Predicate Devices	Implantium II (510(k) No: K060501)

7. Device Description

The DIO UF HSA Internal Sub-Merged Implant System is comprised of dental implants, superstructures, instruments for prosthetics and surgical instruments.

The DIO UF HSA Internal Sub-Merged Implant System is specially designed for use in dental implant surgery. A successfully osseointegrated implant will achieve a

firm implant when surgically implanted under controlled conditions, per well known clinical studies. There are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations.

The DIO UF HSA Internal Sub-Merged Implant System, fixtures are made of commercial pure titanium, grade 4(ASTM F67) which have a S.L.A (Sand-blasted Large grit Acid-etched) treated surface. These fixtures can be used one-stage surgery method or two-stage surgery method. And that are surgically inserted into the upper and/or lower jaw bone. The fixtures replace tooth root as providing a stable foundation for restorations. The fixtures have the diameter(3.8 ~ 7.0mm)and length.(7 ~ 16mm)

Geometrically, the implant is screw-type. An abutment is connected to the implant through a tapered-joint.

The device functions by being surgically implanted in the bone of the upper or lower jaw arches in order to provide support for a prosthetic device, such as an artificial tooth, in order to restore a patient's chewing function.

With regard to the scientific concepts that form the basis for the device, root-form endosseous dental implant devices are characterized by four geometrically distinct types. The DIO UF HSA Internal Sub-Merged Implant System is a screw endosseous dental implant. With regard to the physical and performance characteristics of The DIO UF HSA Internal Sub-Merged Implant System, the design shape, engaging method, implant surface treatment and dimensions (lengths and diameters) are the same as the lawfully marketed predicate device.

Test performed in air at 24℃, at 14Hz frequency for at least 5×10^6 cycles. Tilting angles of specimen is 35°. The fatigue limit is over 250N (Fracture or cracks or severe distortion of any parts were not detected.). It is the same fatigue limit of predicate device.

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Substantial Equivalence Comparison

There are no known technological differences between the DIO UF HSA Internal Sub-Merged Implant System and Implantium II.

	Subject Device	Predicate Device
Manufacturer Name	DIO Corporation	Dentium Co., Ltd.
Device Name	DIO UF HSA Internal Sub-Merged Implant System	Implantium II
Intended Use	The DIO UF HSA Internal Sub-Merged Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading.	Implantium II is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetics devices, such as artificial teeth, and to restore the patient's chewing function.
Fixture Material	CP Ti Gr4 (ASTM F67)	CP Ti Gr4 (ASTM F67)
Design	Internal Type and Morse Tapered	Internal Type and Morse Tapered
Screw Threads	YES	YES

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Implant Diameters(mm)	3.8 ~ 7.0	3.6 ~ 5.0
Implant Lengths(mm)	7 ~ 16	8 ~ 14
Surface Treatment	S.L.A (Sand-blasted Large grit Acid-etched)	S.L.A (Sand-blasted Large grit Acid-etched)
Sterilization Method	Gamma	Gamma
Abutment Diameters(mm)	4.0 ~ 7.5	4.5 ~ 7.5
Abutment Cuff Lengths(mm)	1.5 ~ 5.5	1.0 ~ 5.5
Abutment Angulation(°)	Max. 25°	Max. 25°
Abutment Surface Treatment	Machined type	TiN Coating
Abutment Sterilization Method	Non Sterilization	Non Sterilization
Abutment Material	CP Ti Gr3, Gr4 (ASTM F67) Ti Alloy(ASTM F136:Ti-6Al-4V ELI)	CP Ti Gr2, Gr3, Gr4 (ASTM F67)
Attachments	Various abutments and components	Various abutments and components

8. Indication for use

The DIO UF HSA Internal Sub-Merged Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller (Ø3.8 ~ Ø5.5) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger (Ø6.0 ~ Ø7.0) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.

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9. Review

The DIO UF HSA Internal Sub-Merged Implant System has same material and similar indication for used, design and technological characteristics as the predicate device.

The DIO UF HSA Internal Sub-Merged Implant System has been subjected to safety, performance and product validation prior to release. Safety tests including biocompatibility has been performed to ensure the devices comply with the applicable International and US regulations.

10. Summary of nonclinical testing

Fatigue testing was conducted according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the DIO HSA STEADY Internal Sub-Merged Fixture and an angled abutment.

Therefore, the fatigue test result of DIO UF HSA Internal Sub-Merged Implant System performs as intended.

11. Conclusion

The evaluation of the DIO UF HSA Internal Sub-Merged Implant System does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to its predicate device.

Date : Feb/ 15/ 2013

Gab-moon,Jeong/ DIO Corporation RA Staff

Date : Feb/ 15/ 2013

Tim C.J. Lee/ DIO, USA Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2013

DIO Corporation
C/O Mr. Timothy C.J. Lee
Manager
DIO USA
3540 Wilshire Boulevard, #1104
LOS ANGELES CA 90010

Re: K122519
Trade/Device Name: DIO UF HSA Internal Sub-Merged Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: DZE, NHA
Product Code: II
Dated: May 6, 2013
Received: May 6, 2013

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(K) Number (if known): K122519

Device Name : DIO UF HSA Internal Sub-Merged Implant System

Indications For Use:

The DIO UF HSA Internal Sub-Merged Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller (Ø3.8 ~ Ø5.5) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger (Ø6.0 ~ Ø7.0) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.

Prescription Use ✔ AND/OR _____ Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.05.21 10:55:10 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122519